REMARKS

In response to the Office Action dated October 4, 2007, Applicants respectfully request that the above amendments be entered and the following remarks be considered. Claims 1-3, 7-14, 17, 18 and 21-24 were pending in the application. Claims 2, 3 and 12 have been canceled. Claims 1, 7-11, 13-14, 17, 18 and 21-24 are believed to be in condition for allowance and such favorable action is respectfully requested.

Objections

Claims 2, 3, and 12 have been objected to as appearing not to limit the base claim. Applicants have canceled these claims and as such request withdrawal of the objection.

Claim rejections 35 USC § 101

Claims 1-3, 7-14, 17, 18 and 21-24 have been rejected under 35 USC § 101 stating the claimed invention lacks credible utility. The Office action points to Ferguson, et al., 31 GUT 1341 (1990) and O'Mahoney et al., 99 CLIN. EXP. IMMUNOL. 70 (1995) as not supporting the claimed utility of the claimed invention. Applicants respectfully traverse this rejection and assert that the claimed invention has patentable utility.

According to MPEP 2107.01 "[p]ractical utility is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980)." Applicants submit that the method for testing a fecal sample for an elevated level of anti-neutrophil cytoplasmic antibodies, wherein an elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis provides a benefit to the public and is consistent with the logic underlying Applicants' assertion.

According to the Office Action, the Ferguson reference found no statistically significant difference in fecal IgA concentration between patients with ulcerative colitis and Crohn's disease. However, Applicants submit that they have obtained FDA approval for an ELISA for the qualitative detection of antibodies, in particular anti-*S. cervisiae* antibodies (ASCA), in feces to aid in the diagnosis of Crohn's disease. Applicants respectfully submit that the FDA approval of a diagnostic assay for detecting antibodies in feces is strong evidence Applicants have been able to develop diagnostic techniques that are more sensitive than those described in the Ferguson reference such that antibodies may be detected in feces in such a way that that particular antibodies are specific to a particular disease state. A copy of the FDA approval of the diagnostic assay is attached hereto.

According to the Office Action, the O'Mahoney reference found fluctuations in fecal antibody depend on the consistency of the feces thus not supporting the claimed utility. However, as can be seen from the specification of the current application, the results for testing feces samples for ANCA were consistent across solid and liquid forms of feces. *See* Specification ¶[0018]. Furthermore, the diagnostic testing for ANCA was performed on patient samples who had already been clinically diagnosed with ulcerative colitis, Crohn's disease or irritable bowel syndrome (IBS) using known techniques such as endoscopy and histological analysis. See Specification [0004] and [0017]. As such, the clinical study was performed according to proper scientific standards and controls. This further supports Applicants the assertion that Applicants have been able to develop diagnostic techniques that are more sensitive than those described in O'Mahoney and that the claimed invention and supports the claimed utility.

In the present application, if a patient's sample contains elevated level of anti-neutrophil cytoplasmic antibodies, the elevated level of anti-neutrophil cytoplasmic antibodies is

an indicator of ulcerative colitis. Thus, while not all patients with UC have an elevated level of ANCA, those who do have an elevated level can be diagnosed with UC, rather than Crohn's disease. Thus, while the test only detects ANCA in 41% of UC patients (Sensitivity), in the 41% of the patients who have ANCA, the test is 92% accurate in diagnosing UC (Specificity). The specificity refers to how well a positive result of ANCA correlates to a diagnosis of UC. For many patients with IBD (UC or CD) a correct diagnosis of UC or CD is difficult and may take many years to complete. The claimed invention is certainly useful to those patients who have struggled to find a diagnosis for their disease and now can begin the proper treatment based on their diagnosis of UC utilizing the diagnostic test for ANCA. For those patients, the claimed invention certainly has a credible utility.

Furthermore, according to MPEP 2107.01, "[p]ractical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be 'useful.' Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is 'useful' for a particular reason." Applicants respectfully submit that the invention as claimed is "useful" as described above and request withdrawal of the §101 rejection of claims 1, 7-11, 13-14, 17-18 and 21-24.

Claim rejections 35 USC § 112

Claims 1, 7-11, 13-14, 17-18 and 21-24 have been rejected under §112, first paragraph as not being supported by credible utility and that one skilled in the art would not know how to make and use the invention. As discussed above, the claims are useful and have a credible utility. Furthermore, one skilled in the art would understand how to make and use the invention. As such, Applicants request withdrawal of the §112 rejection of the claims.

CONCLUSION

Each of claims 1, 7-11, 13-14 and 17, 18 and 21-24 is believed to be in condition for allowance, and a timely notice of allowance solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

The fee for a three-month extension of time is submitted herewith. It is believed that no additional fee is due in conjunction with the present Amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required or credit any overpayment, to Deposit Account No. 19-2112, referencing attorney docket number TLAB.100294.

Respectfully submitted,

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